

## **REMARKS**

This is a Supplemental Response to the final Office Action mailed December 31, 2007, the Advisory Action mailed March 19, 2008, the Examiner interview of March 25, 2008, and the Advisory Action mailed on June 24, 2008. Applicants respectfully request reconsideration of the present application in view of the above amendments and following remarks.

The final Office Action address claims 1-8, 10-14, 16-27, and 32-34, which are currently pending. Each of these claims stand rejected under 35 U.S.C. § 103. Claims 9, 15, and 28 were previously canceled. Claims 29-31 were previously withdrawn.

In a Supplemental Response filed on May 15, 2008, Applicants proposed amending independent claims 1 and 19 and canceling claims 22 and 34. However, according to the Advisory Action mailed on June 24, 2008, the proposed claim amendments were not entered.

Accordingly, in this timely filed response, Applicants now request that the above claim amendments be entered in conjunction with the filing of a Request for Continued Examination. Further, Applicants request allowance of each of pending claims 1-8, 10-14, 16-21, 23-27, 32, and 33.

### ***Amendments to the Claims***

As suggested by the Examiner in the Advisory Action mailed March 19, 2008, Applicants amend independent claims 1 and 19 to recite that the nonwoven polymeric material has a density in the range of about 120 mg/cc to 360 mg/cc. Support for these amendments can be found throughout the specification, for example, at Paragraph [0048] of the published application. Claim 34 is canceled. Applicants also amend independent claim 19 to include the features recited in claim 22. Claim 22 is canceled. No new matter is added.

### ***Rejections Pursuant to 35 U.S.C. § 112***

In the final Office Action, the Examiner rejects claims 1-8, 10-14, 16-27, and 32-34 under 35 U.S.C. § 112, second paragraph, as being indefinite. In the Advisory Action mailed on June 24, 2008, the Examiner agrees that the current amendments reciting that the nonwoven polymeric material has a density in the range of about 120 mg/cc to 360 mg/cc are sufficient to overcome this rejection. Accordingly, Applicants obviate the Examiner's rejection.

***Rejections Pursuant to 35 U.S.C. § 103***

In the final Office Action, the Examiner rejects claims 1-8, 10-14, 16-27, and 32-34 pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2002/0127265 of Bowman et al. (“Bowman”), in view of International Patent Publication No. WO 01/85226 of Huckle et al. (“Huckle”), and exemplified by Boland et. al. (*J. Macromol. Sci.-Pure Appl. Chem.*, 2001, A38(12), p 1231-1243) (“Boland”). In the Advisory Action mailed on June 24, 2008, the Examiner asserts that further consideration and search with respect to this rejection is needed in light of the amendments herein. Although Applicants understand that the Examiner’s request for further consideration and search indicates that the amendments obviate the obviousness rejection, Applicants reiterate the arguments presented in the Supplemental Response filed on May 15, 2008, with respect to patentability in view of Bowman, Huckle, and Boland.

Claims 1 and 19 each recite, in part, that the scaffold includes a “nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc.” Bowman discloses “a mesh reinforcing material.” (Bowman at Paragraph [0066].) In the Advisory Action mailed March 19, 2008, the Examiner argues that “although Bowman does not recite the density of their nonwoven scaffolds in units of mg/cc, [Bowman] provides sufficient evidence that such a density is a testable physical property.” However, the method of density evaluation disclosed by Bowman relates only to the evaluation of the density of mesh materials, not nonwoven polymeric materials as claimed. Although the Examiner discusses the methods of measuring mesh density disclosed by Bowman, Applicants submit that the Examiner has not made out a *prima facie* case of equivalence. (See MPEP 2183.) In particular, the Examiner failed to provide an explanation and rationale as to why the mesh material disclosed by Bowman is an equivalent of the nonwoven polymeric material of the instant invention. Moreover, the Examiner failed to provide an explanation and rationale as to why the *density* of Bowman’s mesh would be equivalent to the claimed nonwoven polymeric material *density*. The mere fact that the density of Bowman’s mesh “is a testable physical property” does not support the contention that Bowman’s mesh is equivalent to the claimed nonwoven polymeric material or that the density of Bowman’s mesh would be equivalent to the density of the claimed nonwoven polymeric material. Indeed, Applicants disclose that “[t]he term ‘nonwoven’ as used in the present invention, and as understood by one skilled in the art, *does not include woven, knit, or mesh fabrics.*” (See Published Application at Paragraph [0048].) (Emphasis added.) Furthermore, Bowman discloses that a “low density, or open knitted mesh material, is preferred.” (See Bowman at Paragraph

[0066].) Thus, not only does the instant specification suggest that Bowman's mesh is not equivalent to the claimed nonwoven polymeric material, the teachings of Bowman also tend to show nonequivalence. (See MPEP 2184.) Finally, Bowman also fails to teach or suggest that the mesh material has a density in the claimed range.

Claims 1 and 19 also recite that the scaffold has an initial modulus of elasticity greater than about 1.5 MPa. Bowman does not teach or suggest a scaffold having the claimed modulus of elasticity. Indeed, in the previous Office Action dated May 4, 2007, the Examiner admitted that Bowman "does not explicitly teach the specific modulus of elasticity...of the claimed scaffold."

In the Advisory Action mailed March 19, 2008, the Examiner relies on the disclosure of Bowman at paragraph [0031] to argue that "because the modulus of elasticity is the ratio of stress to strain, the '265 publication provides sufficient evidence to suggest that, absent evidence to the contrary, the scaffolds taught therein will have a modulus of elasticity greater than about 1.5 MPa, based on the stress and strain requirements set forth in [Bowman]." This is incorrect. As discussed with the Examiner during the telephone conference of March 25, 2008, Bowman does not set forth any strain requirements. Paragraph [0031] of Bowman discloses "suitable elastomers exhibit a high percent elongation and a low modulus, while possessing good tensile strength and good recovery characteristics." Although paragraph [0031] also discloses that "suitable elastomers should also have a tensile strength greater than about 500 psi, preferably greater than about 1,000 psi, and a tear strength of greater than about 50 lbs/inch, preferably greater than about 80 lbs/inch," there is no disclosure of a strain requirement. Furthermore, the disclosed values of tensile strength and tear strength are insufficient to determine a modulus of elasticity. Modulus of elasticity is the ratio of stress to strain. (See "Machinery's Handbook," Green, 25<sup>th</sup> edition, Industrial Press Inc., 1996, pages 192-193, copies enclosed.) Therefore, a determination of the modulus of elasticity can only be made if a value of strain is known. Strain is a dimensionless quantity defined as "the amount by which a dimension of a body changes when the body is subjected to a load, divided by the original value of the dimension." (*Id.*) None of the values provided by Bowman in paragraph [0030] are a strain or can be used to calculate a modulus of elasticity. Thus, Bowman fails to provide any evidence to suggest that the elastomers taught therein will have a modulus of elasticity greater than about 1.5 MPa as required by claims 1 and 19. Indeed, paragraph [0031] mentions a "low modulus" in the context of a material with a high percent elongation and good recovery characteristics, properties that indicate the elastomers disclosed by Bowman have good characteristics when stretched and are relatively flexible.

Paragraph [0031] therefore suggests, if anything, that the modulus of elasticity of the elastomers disclosed by Bowman would be lower than the claimed range.

Accordingly, claims 1 and 19 distinguish over the combination of Bowman and Huckle and represent allowable subject matter. Claim 34 is canceled, thereby obviating the Examiner's rejection thereto. Claims 2-8, 10-14, 16-18, 20-27, and 32-33, which depend from claims 1 and 19, distinguish over the cited art at least because they depend from an allowable base claim.

***Obviousness-Type Double Patenting Rejections***

In the final Office Action, the Examiner provisionally rejected claims 1-8, 10-14, 16-27, and 32-33 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-14, 17-29, and 32 of co-pending Application No. 11/427,477. In the Advisory Action mailed on June 24, 2008, the Examiner states that this rejection is still pending.

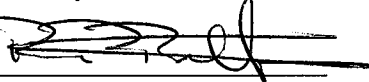
Applicants believe that all pending claims are allowable. The instant application was filed earlier than the application that forms the basis of the non-statutory double patenting rejection, and thus the Examiner should withdraw the provisional rejection and permit this application to issue as a patent without a terminal disclaimer (MPEP §804).

***Conclusion***

Applicants submit that all pending claims are allowable, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed necessary to expedite prosecution of this application.

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Respectfully submitted,

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